PainWeek

The Regulatory Agency Will See You Now

Kevin L. Zacharoff, MD

PainWeek

Disclosures

Nothing to Disclose

Learning Objectives

- Identify pain treatment-related regulatory agencies
- Discuss the changing role of regulatory agencies in today's pain management environment
- Review similarities and differences between regulatory approaches to prescribing practices
- Discuss the negotiation between regulatory forces and practical clinical aspects of managing patients with chronic pain

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What is a Regulatory Agency?

- A regulatory agency is a **public authority or government agency** responsible for exercising some kind of autonomous authority over some area of human activity in a regulatory or supervisory capacity
  - Also know as:
    - Regulatory Authority
    - Regulatory body
    - Regulator

significant OTHER

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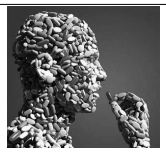
Regulatory Scrutiny?



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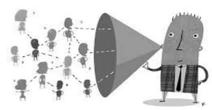
The Facts

It's a Crowded Field

The Facts





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Who Does What?

The Facts

Centers for Medicare and Medicaid (CMS)

- **Oversee most of the regulations** related directly to the health care system
- Provides government-subsidized medical coverage through a number of programs:
  - Medicare
  - Medicaid
  - State Children's Health Insurance Program (SCHIP)
  - Health Insurance Portability and Accountability Act (HIPPA)

CMS.gov
Centers for Medicare & Medicaid Services

Nancy Grimm. Healthcare Regulations: Who Does What? December, 2014. http://www.yourtrainingprovider.com/blog_main/bid/203291/health-care-regulation-who-does-what. Accessed July 13, 2017.

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Who Does What?

The Facts

- **The Agency for Healthcare Research and Quality (AHRQ)**
  - Conducts research
  - Develops education
  - Generates measures and data
  - Goals include:
    - **Reducing costs**
    - **Improving safety**
    - Decreasing medical errors

AHRQ
Advancing Excellence in Health Care

Nancy Grimm. Healthcare Regulations: Who Does What? December, 2014. http://www.yourtrainingprovider.com/blog_main/bid/203291/health-care-regulation-who-does-what. Accessed July 13, 2017.

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Who Does What?

The Facts

- **The Joint Commission**
  - The Joint Commission **accredits and certifies nearly 21,000 health care organizations** and programs in the United States
  - Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards

https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx . Accessed July 13, 2017.

The Joint Commission

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Who Does What?

The Facts

- **The National Committee for Quality Assurance (NCQA)**
  - **Helps to build consensus around important healthcare quality issues** and to decide what's important, how to measure it, and how to promote improvement by working with:
    - Large employers
    - Policymakers
    - Healthcare providers
    - Patients
    - Health plans

http://www.ncqa.org/newsroom/details/ncqa-seeks-publics-help-on-new-and-revised-measures?ArtMID=11280&ArticleID=66&tabid=2659. Accessed July 13, 2017.

NCQA
Measuring quality.
Improving health care.

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Who Does What?

The Facts

- **The Office of National Drug Control Policy (ONDCP)**
  - **Works to reduce drug use and its consequences** by leading and coordinating the development, implementation, and assessment of U.S. drug policy
  - In addition to its vital ongoing work, ONDCP also provides administrative and financial support to the **President's Commission on Combating Drug Addiction and the Opioid Crisis**

Executive Office of the President of the United States

https://www.whitehouse.gov/ondcp/about. Accessed July 13, 2017.

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The Facts

Who Does What?

- **The Environmental Protection Agency (EPA)**
  - Mission is to **protect human health and the environment**
  - Plays an integral role in U.S. policies concerning natural resources, human health, economic growth, energy, transportation, agriculture, industry, and international trade
  - Ensuring that federal laws **protecting human health and the environment** are enforced fairly and effectively

https://www.epa.gov/ocir/hearings. Accessed July 13, 2017.

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The Facts

Who Does What?

The Drug Enforcement Administration (DEA)

- Enforces controlled substances laws and regulations as they pertain to the manufacture, distribution, and dispensing of **legally produced** controlled substances
- Brings criminal and civil justice actions against organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for **illicit traffic** in the U.S.

https://www.dea.gov/docs/publication.shtml. Accessed July 13, 2017.

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The Facts

Who Does What?

- **The Federation of State Medical Boards (FSMB)**
  - Represents the **70 state medical and osteopathic regulatory boards** (state medical boards)
  - Supports its member boards as they fulfill their mandate of protecting the public's health, safety and welfare through the proper **licensing**, **disciplining**, and **regulation** of physicians and, in most jurisdictions, other healthcare professionals

https://www.fsmb.org/about-fsmb/fsmb-overview/. Accessed July 13, 2017.

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Who Does What?

The Facts

- **The Centers for Disease Control and Prevention (CDC)**
  - Main goal is to **protect public health and safety** through the **control and prevention of disease**, injury, and disability in the US and internationally
  - Focuses mainly on infectious disease, food borne pathogens, environmental health, occupational safety and health, health promotion, injury prevention and educational activities designed to improve the health of United States citizens
  - **Researches and provides information on non-infectious diseases** is a founding member of the International Association of National Public Health Institutes

http://www.cdc.gov/about/history/organizations.htm. Accessed July 13, 2017.

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CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Who Does What?

The Facts

- **The Food and Drug Administration (FDA)**
  - Responsible for **protecting the public health** by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices
  - Ensures the safety of our nation's food supply, cosmetics, and products that emit radiation

http://www.fda.gov/AboutFDA/WhatWeDo/default.htm. Accessed July 13, 2017.

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FDA U.S. FOOD & DRUG ADMINISTRATION

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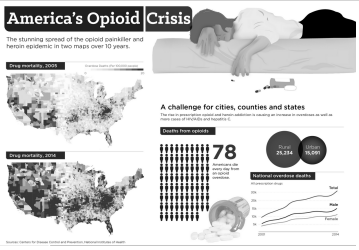
So What?

So What?

The Facts



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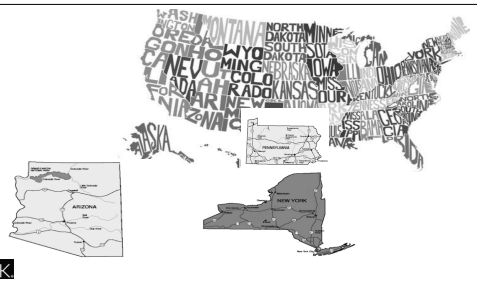
So What?

The Implications



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So What?

The Implications

This is an important message from the Board delivered to your registered primary email address

Dear Arizona Physicians:

On June 5, 2017, Governor Ducey declared a state of emergency due to the opioid epidemic. Also in response to this statewide emergency, Governor Ducey issued Executive Order 2017-04, *Enhanced Surveillance Advisory*.

Attached please find a link to a letter from Cara Christ, M.D. M.S., Director of the Department of Health Services, informing the medical community of the new requirements related to reporting suspected opioid overdoses and deaths.

This is one of the first steps in gathering important data to assist in assessing the problem and devising strategies to combat this serious health epidemic.

Very truly yours,

Patricia McSorley, J.D.
Executive Director
Arizona Medical Board

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So What?

The Implications

Governor Ducey Declares Statewide Health Emergency In Opioid Epidemic June 5, 2017

News Release

Newly released data from the Arizona Department of Health Services shows in 2016, 790 Arizonans died from opioid overdoses — an average of more than two people per day. The trend shows an alarming increase of 74 percent over the past four years. Today's declaration by the governor directs the Arizona Department of Health Services to rapidly respond to this public health emergency.

- prevent prescription opioid drug abuse through appropriate prescribing practices,
- develop guidelines to educate healthcare providers on responsible prescribing practices,
- expand access to treatment, especially Medication Assisted Treatment (MAT), and
- reverse overdoses through the distribution of naloxone.

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https://azgovernor.gov/governor/news/2017/06/governor-ducey-declares-statewide-emergency-opioid-epidemic . Accessed July 14, 2017.

The Implications

Dear Partner,

On June 5, 2017, Arizona Governor Doug Ducey declared a Public Health State of Emergency due to the opioid epidemic. The declaration directs Arizona Department of Health Services to lead the statewide emergency response.

Pursuant to A.R.S. §36-782, an Enhanced Surveillance Advisory has been issued to track opioid morbidity and mortality. **Required reporting within 24 hours of the items below will go into effect June 15, 2017.**

Required Reporters	Health condition to be reported	Reporting System
Healthcare professionals licensed under A.R.S. Titles 32 and 36	• Suspected opioid overdoses • Suspected opioid deaths • Neonatal abstinence syndrome	**MEDSIS** Training: www.azhealth.gov/opioidtraining New Account: MedsisHelpDesk@siren.az.gov
Administrators of a healthcare institution or correctional facility	• Suspected opioid overdoses • Suspected opioid deaths • Neonatal abstinence syndrome	**MEDSIS** Training: www.azhealth.gov/opioidtraining New Account: MedsisHelpDesk@siren.az.gov
Emergency Medical Services/Ambulance agencies (first response agencies, ground and air ambulance agencies)	• Suspected opioid overdoses • Suspected opioid deaths • Naloxone doses administered	**AZ-PIERS** Training: www.azhealth.gov/opioidtraining New Account: Anne.Vossbrink@azdhs.gov
Law enforcement officers	• Suspected opioid overdoses • Suspected opioid deaths • Naloxone doses administered	**AZ-PIERS** Training: www.azhealth.gov/opioidtraining New Account: Anne.Vossbrink@azdhs.gov
Medical examiners	• Suspected opioid deaths	**MEDSIS** Training: www.azhealth.gov/opioidtraining New Account: MedsisHelpDesk@siren.az.gov
Pharmacists	• Naloxone doses dispensed	**Prescription Drug Monitoring Program (PDMP)** Training: https://azpa.learningexpressce.com/index.cfm?fa=view&eventID=8362 New Account: https://pharmacypmp.az.gov/

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NYS – PMP

The Implications

- Internet System for Tracking Over-Prescribing
  - Effective August 27th, 2013, most prescribers are required to consult the **Prescription Monitoring Program (PMP) Registry** when writing prescriptions for Schedule II, III, and IV controlled substances
  - The registry provides practitioners with direct, secure access to view dispensed controlled substance prescription histories for their patients
  - The PMP is available 24 hours a day/7 days a week via an application on the Health Commerce System (HCS) at https://commerce.health.state.ny.us
  - Reports include all controlled substances that were dispensed in New York State and reported by the pharmacy/dispenser for the past six months
  - This information allows practitioners to better evaluate their patients' treatment with controlled substances and determine whether there may be abuse or non-medical use

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So What?

The Implications

ELECTRONIC PRESCRIBING

Revised: November 2016

NEW YORK state department of HEALTH

NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Narcotic Enforcement
1-866-811-7957
www.health.ny.gov/professionals/narcotic

Q2: Is Electronic Prescribing mandatory for New York State practitioners?

A2: As of March 27, 2016 it will be mandatory for practitioners, excluding veterinarians, to issue electronic prescriptions for controlled and non-controlled substances. Electronic prescribing of controlled substances will require additional security features and registration of the certified software application with the Bureau of Narcotic Enforcement.

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So What?

The Implications

NEW YORK STATE OF OPPORTUNITY. | Department of Health

ANDREW M. CUOMO Governor | **HOWARD A. ZUCKER, M.D., J.D.** Commissioner | **SALLY DRESLIN, M.S., R.N.** Executive Deputy Commissioner

Mandatory Prescriber Education Guidance

Prescribers licensed under Title Eight of the Education Law in New York to treat humans and who have a DEA registration number to prescribe controlled substances, as well as medical residents who prescribe controlled substances under a facility DEA registration number, must complete at least three (3) hours of course work or training in pain management, palliative care, and addiction. The course work or training must be completed by July 1, 2017, and once every three years thereafter, pursuant to Public Health Law (PHL) §3309-a(3).

The course work or training may be live or online.

The course work or training must include the following eight (8) topics:

- New York State and federal requirements for prescribing controlled substances;
- Pain management;
- Appropriate prescribing;
- Managing acute pain;
- Palliative medicine;
- Prevention, screening and signs of addiction;
- Responses to abuse and addiction; and
- End of life care.

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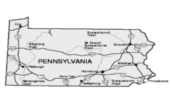
So What?

The Implications



pennsylvania
DEPARTMENT OF HEALTH
PRESCRIPTION DRUG MONITORING PROGRAM

In case you missed it – New PA PDMP requirements for prescribers.

New legislative changes to the Pennsylvania Prescription Drug Monitoring Program (PA PDMP) went into effect on Jan. 1, 2017.

Here is what you need to know:

- **Prescribers** must now query the PA PDMP **each time** a patient is prescribed an opioid drug product or benzodiazepine by the prescriber. There are exceptions for emergency departments and for patients who are admitted to a health care facility, and these can be found on our website's Frequently Asked Questions (FAQ) page.
- **Dispensing practitioners** must now submit data to the PA PDMP no later than the close of the subsequent business day (Monday through Friday) after dispensing the controlled substance, as opposed to the previous requirement of within 72 hours.

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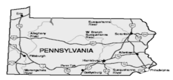
So What?

The Facts



pennsylvania
DEPARTMENT OF HEALTH
PRESCRIPTION DRUG MONITORING PROGRAM

Pennsylvania Prescription Drug Monitoring Program Now Sharing Data with 11 Other States and D.C.

The Pennsylvania Prescription Drug Monitoring Program (PA PDMP) has now connected with 11 other states in an effort to foster data sharing among PDMPs. Interstate sharing of data helps prescribers and pharmacists get a more complete picture of their patients' controlled substance prescription histories, regardless of which state they filled their prescription in.

Users of the PA PDMP can now see if their patients have filled controlled substance prescriptions in: Connecticut; Illinois; Louisiana; Massachusetts; New Jersey; New York; Ohio; Texas; Virginia; West Virginia; and Washington D.C. Additionally, a one-way sharing connection has been established with Maryland, enabling their program users to search the PA PDMP. The PA PDMP Office invites all other states to begin sharing data, and anticipates that Pennsylvania will connect with more state PDMPs in the upcoming weeks.

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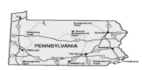
So What?

The Implications



http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/M-P/opioids/Pages/Prescribing-Guidelines.aspx#.WWkCxVGQyHs. Accessed July 14, 2017.

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So What?

The Implications

- **Maine**
  - **January 1, 2017**
    - Mandatory check of PDMP
    - Limits on opioid prescribing for
    - acute and chronic pain
  - **July 1, 2017**
    - Mandatory electronic prescribing
    - Patients with active prescriptions in excess of 100 morphine milligram equivalents must be tapered
  - **December 31, 2017**
    - CME requirement for prescribers

www.maine.gov/dhhs/samhs/osa/help/Documents/SessionB_Smith.pdf . Accessed July 15, 2017.

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The Role of Regulatory Agencies

The Role of Regulatory Agencies

The Facts

January 5, 2017 — Centers for Medicare & Medicaid Services (CMS) Opioid Misuse Strategy

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) OPIOID MISUSE STRATEGY 2016

CMS has made attacking this devastating epidemic a top priority and is providing help and resources to clinicians, beneficiaries, and families. This is an ongoing CMS strategy, as part of the HHS Opioid Initiative launched in March 2015, to combat misuse and promote programs that support treatment and recovery support services. The CMS effort includes four priority areas:

1. *Implement more effective person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion;*
2. *Expand naloxone use, distribution, and access, when clinically appropriate;*
3. *Expand screening, diagnosis, and treatment of opioid use disorders, with an emphasis on increasing access to medication-assisted treatment; and*
4. *Increase the use of evidence-based practices for acute and chronic pain management.*

HHS.gov News. (2016). HHS takes strong step to address opioid drug related overdose, death and dependence. http://www.hhs.gov/about/news/2016/03/21/hhs-takes-strong-step-to-address-opioid-drug-related-overdose-death-and-dependence.html. Accessed July 14, 2017

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The Role of Regulatory Agencies

The Facts

AHRQ Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

- **Supporting the Department of Health and Human Services Initiative**
  - Increasing the evidence base with research and data
  - Investing ~$12 million over next 3 years to explore how to best support rural primary care practices using medication-assisted therapy and overcoming educational barriers

https://www.ahrq.gov/professionals/systems/primary-care/opioids/index.html. Accessed July 14, 2017

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The Role of Regulatory Agencies

The Implications

SAFE USE OF OPIOIDS IN HOSPITALS

- Create and implement policies and procedures for the ongoing clinical monitoring of patients receiving opioid therapy
- Create and implement policies and procedures that allow for a second level review by a pain management specialist or pharmacist
- Track and analyze opioid-related incidents
- Use information technology to monitor prescribing
- Advise clinicians who prescribe pain medications to use both pharmacologic and non-pharmacologic alternatives
- Educate and assess the understanding of staff
- Educate and provide written instructions to patients on opioids
- Assess the organization's need for training based on the analysis of reported adverse events, near misses and staff observations

The Joint Commission Sentinel Event Alert

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The Role of Regulatory Agencies

The Implications

- **Proposes new measures to assess potentially inappropriate use of opioids:**
  - Assesses whether health plan members 18 years and older receive:
    - Long-term opioids at high dose
    - Opioids from multiple prescribers or multiple pharmacies
    - Long-term, high-dose opioids from multiple prescribers and multiple pharmacies

NCQA Measuring quality. Improving health care.

http://www.ncqa.org/newsroom/details/ncqa-seeks-publics-help-on-new-and-revised-measures?ArtMID=11280&ArticleID=66&tabid=2659 . Accessed July 14, 2017

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The Role of Regulatory Agencies

The Facts

President's Commission on Combating Drug Addiction and the Opioid Crisis

- Mission
  - To study the scope and effectiveness of the Federal response to drug addiction and the opioid crisis and to make recommendations to the President for improving that response including
    - Availability of addiction treatment and drug reversal
    - Best practices for prevention including education and PDMPs

https://www.whitehouse.gov/ondcp/presidents-commission/mission. Accessed July 15, 2017

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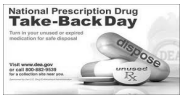
The Role of Regulatory Agencies

The Implications

Collecting and Disposing of Unwanted Medicines

What to do with Unwanted or Expired Medicines

- Guidelines for **disposal**
- **Take-back** Events or Programs



https://www.epa.gov/hwgenerators/collecting-and-disposing-unwanted-medicines. Accessed July 15, 2017

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The Role of Regulatory Agencies

The Implications

HEADQUARTERS NEWS

October 04, 2016
Contact: DEA Public Affairs
(202) 307-7977

DEA Reduces Amount of Opioid Controlled Substances to be Manufactured in 2017

- The United States Drug Enforcement Administration (DEA) has reduced the amount of almost every Schedule II opiate and opioid medication that may be manufactured in the United States in 2017 by 25 percent or more
- The purpose of quotas are to provide for the adequate and uninterrupted supply for legitimate medical need of the types of schedule I and II controlled substances that have a potential for abuse, while limiting the amounts available to prevent diversion

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https://www.dea.gov/divisions/hq/2016/hq100416.shtml. Accessed July 15th 2017

The Role of Regulatory Agencies

The Facts

Federation of STATE MEDICAL BOARDS

MODEL POLICY ON THE USE OF
OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN
Adopted as policy by the House of Delegates of the Federation of State Medical Boards in July 2013

- To provide state medical boards with an updated guideline for assessing physicians' management of pain
- To determine whether opioid analgesics are used in a manner that is both medically appropriate and in compliance with applicable state and federal laws and regulations

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The Implications

The Role of Regulatory Agencies

- **Consider treatment inappropriate including but not limited to:**
  - Inadequate attention paid to **initial assessment and risk determination**
  - **Inadequate monitoring** of potential for aberrant drug-related behaviors and use of available tools
  - Inadequate attention to **patient education and informed consent**
  - Unjustified **dose escalation**
  - Excessive reliance on opioid analgesics (particularly **high doses**)

Federation of STATE MEDICAL BOARDS

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The Role of Regulatory Agencies

The Implications

CDC Centers for Disease Control and Prevention

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 65 March 15, 2016

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

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The Implications

The Role of Regulatory Agencies

- **Guidelines**
  - **Non-pharmacologic** therapy and **non-opioid** pharmacologic therapy are preferred for chronic pain
  - Before starting opioid therapy for chronic pain, clinicians should **establish treatment goals** with all patients
  - Discuss known **risks, benefits, and responsibilities** with patients
  - **Immediate-release opioids** first

CDC Centers for Disease Control and Prevention

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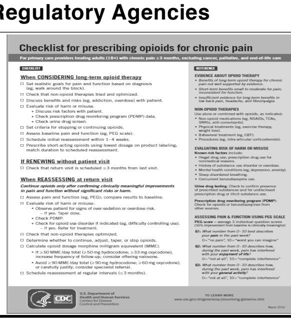
The Role of Regulatory Agencies

- **Guidelines (Cont'd)**
  - **Lowest effective dosage**
    - Reassess risk/benefit if **≥50 MME/day**
    - Avoid or carefully justify **≥90 MMD/day**
  - In acute pain, **lowest effective dose, lowest quantity**
  - **Re-evaluate risk/benefit** in 1-4 weeks, then every 3 months
  - Utilize strategies that **mitigate risk**
    - **Opioid risk assessment**
    - **Naloxone**

The Role of Regulatory Agencies

- **Guidelines (Cont'd)**
  - Check the **PDMP**
  - **Urine drug testing** before initiation
    - At least annually
  - Avoid concurrent opioids and **benzodiazepines**
  - Offer or arrange for evidence-based treatment for patients with **opioid use disorder**

The Role of Regulatory Agencies



Checklist for prescribing opioids for chronic pain

For primary care providers treating adults (18+) with chronic pain ≥3 months, excluding cancer, palliative, and end-of-life care

CHECKLIST

When CONSIDERING long-term opioid therapy

- ☐ Set realistic goals for pain and function based on diagnosis (eg, walk around the block).
- ☐ Check that non-opioid therapies tried and optimized.
- ☐ Discuss benefits and risks (eg, addiction, overdose) with patient.
- ☐ Evaluate risk of harm or misuse.
  - Discuss risk factors with patient.
  - Check prescription drug monitoring program (PDMP) data.
  - Check urine drug screen.
- ☐ Set criteria for stopping or continuing opioids.
- ☐ Assess baseline pain and function (eg, PEG scale).
- ☐ Schedule initial reassessment within 1–4 weeks.
- ☐ Prescribe short-acting opioids using lowest dosage on product labeling; match duration to scheduled reassessment.

If RENEWING without patient visit

- ☐ Check that return visit is scheduled ≤3 months from last visit.

When REASSESSING at return visit

Continue opioids only after confirming clinically meaningful improvements in pain and function without significant risks or harm.

- ☐ Assess pain and function (eg, PEG); compare results to baseline.
- ☐ Evaluate risk of harm or misuse:
  - Observe patient for signs of over-sedation or overdose risk.
    - If yes: Taper dose.
  - Check PDMP.
  - Check for opioid use disorder if indicated (eg, difficulty controlling use).
    - If yes: Refer for treatment.
- ☐ Check that non-opioid therapies optimized.
- ☐ Determine whether to continue, adjust, taper, or stop opioids.
- ☐ Calculate opioid dosage morphine milligram equivalent (MME).
  - If ≥50 MME/day total (≥50 mg hydrocodone; ≥33 mg oxycodone), increase frequency of follow-up; consider offering naloxone.
  - Avoid ≥90 MME/day total (≥90 mg hydrocodone; ≥60 mg oxycodone), or carefully justify; consider specialist referral.
- ☐ Schedule reassessment at regular intervals (≤3 months).

REFERENCE

EVIDENCE ABOUT OPIOID THERAPY

- *Benefits of long-term opioid therapy for chronic pain not well supported by evidence.*
- *Short-term benefits small to moderate for pain; inconsistent for function.*
- *Insufficient evidence for long-term benefits in low back pain, headache, and fibromyalgia.*

NON-OPIOID THERAPIES

Use alone or combined with opioids, as indicated:

- Non-opioid medications (eg, NSAIDs, TCAs, SNRIs, anti-convulsants).
- Physical treatments (eg, exercise therapy, weight loss).
- Behavioral treatment (eg, CBT).
- Procedures (eg, intra-articular corticosteroids).

EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

- Illegal drug use; prescription drug use for nonmedical reasons.
- History of substance use disorder or overdose.
- Mental health conditions (eg, depression, anxiety).
- Sleep-disordered breathing.
- Concurrent benzodiazepine use.

Urine drug testing: Check to confirm presence of prescribed substances and for undisclosed prescription drug or illicit substance use.

Prescription drug monitoring program (PDMP): Check for opioids or benzodiazepines from other sources.

ASSESSING PAIN & FUNCTION USING PEG SCALE

PEG score = average 3 individual question scores (30% improvement from baseline is clinically meaningful)

Q1: *What number from 0–10 best describes your **pain** in the past week?*
0="no pain", 10="worst you can imagine"

Q2: *What number from 0–10 describes how, during the past week, pain has interfered with your **enjoyment of life**?*
0="not at all", 10="complete interference"

Q3: *What number from 0–10 describes how, during the past week, pain has interfered with your **general activity**?*
0="not at all", 10="complete interference"

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

TO LEARN MORE
www.cdc.gov/drugoverdose/prescribing/guideline.html

March 2016

The Role of Regulatory Agencies

FDA U.S. FOOD & DRUG ADMINISTRATION

PAIN MANAGEMENT AND THE OPIOID EPIDEMIC

BALANCING SOCIETAL AND INDIVIDUAL BENEFITS AND RISKS OF PRESCRIPTION OPIOID USE

July 13, 2017

Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse

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The Facts

The Role of Regulatory Agencies

FDA U.S. FOOD & DRUG ADMINISTRATION

- **Mission**:
  - **Update information** since IOM Report[1]
  - The **evolving role** of opioid analgesics
  - Characterizing the **epidemiology of the opioid epidemic**
    - **Evidence** on strategies for addressing it

1. **Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Institute of Medicine, 2011.**

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The Facts

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- **Identify actions to be taken by FDA and other agencies and organizations**
  - Specifically **incorporating individual and societal considerations into its risk/benefit analysis** framework for approval and post-market surveillance
- **Identify research questions** that need to be addressed to assist the FDA in implementing this framework

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The Facts

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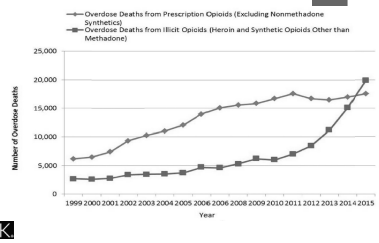

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The Implications

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- **Recommendations**
  - **Invest in research** to better understand pain and opioid use disorder
  - **Consider potential effects of policies and programs** for opioid analgesics on illicit markets
  - Improve **reporting**, invest in **data**, provide **transparency**
  - **Incorporate public health considerations** into FDA decision-making

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The Implications

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- **Recommendations (Cont'd)**
  - Strengthen **post-approval oversight**
  - **Review currently approved** opioid analgesics
  - Establish **comprehensive educational materials** for patients and healthcare providers
  - **Facilitate reimbursement** for comprehensive approaches
  - **Improve PDMP** use and data

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- **Recommendations (Cont'd)**
  - **Evaluate impact** of patient and public education
  - **Expand education and treatment for opioid use disorder**
  - Remove barriers to **insurance coverage** for Tx of opioid use disorder
  - **Leverage pharmacists**
  - Improve access to **naloxone**

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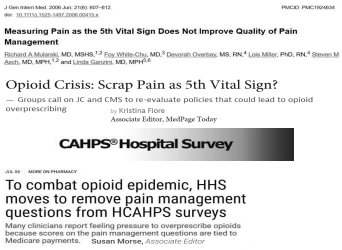
Things May be Changing



J Gen Intern Med. 2006 Jun; 21(6): 607–612.
PMCID: PMC1924634
doi: 10.1111/j.1525-1497.2006.00478.x

Measuring Pain as the 5th Vital Sign Does Not Improve Quality of Pain Management

Richard A Mularski, MD, MSHS,[1,2] Foy White-Chu, MD,[3] Devorah Overbay, MS, RN,[4] Lois Miller, PhD, RN,[4] Steven M Asch, MD, MPH,[1,2] and Linda Ganzini, MD, MPH[2,4]

Opioid Crisis: Scrap Pain as 5th Vital Sign?

— Groups call on JC and CMS to re-evaluate policies that could lead to opioid overprescribing

by Kristina Fiore
Associate Editor, MedPage Today

CAHPS® Hospital Survey

JUL 06 MORE ON PHARMACY

To combat opioid epidemic, HHS moves to remove pain management questions from HCAHPS surveys

Many clinicians report feeling pressure to overprescribe opioids because scores on the pain management questions are tied to Medicare payments. Susan Morse, *Associate Editor*

December 17-18, 2018

RF Regulatory Focus™

Regulatory Focus™ > News Articles > 12 > FDA Advisory Committee Votes for Co-Prescribing Naloxone With Opioids

FDA Advisory Committee Votes for Co-Prescribing Naloxone With Opioids

Posted 18 December 2018 | By Zachary Brennan

With a vote of 12-11, the joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM) voted in favor of adding labeling language that recommends co-prescription of naloxone for all or some patients prescribed opioids.

The close vote was the result of advisory committee members questioning whether co-prescribing necessarily addresses the opioid crisis at hand, while others said that co-prescribing is already the standard of care and therefore should be added to the labeling.

For instance, Kevin Zacharoff of the State University of New York, Stony Brook School of Medicine, voted yes and said he looks at his vote and co-prescribing as a message to health care providers prescribing opioids. "It will promote the discussion" around the use of naloxone, he added.

On the other side, Steven Mezial of Fairview Health Services/Healtheast Care System in Minneapolis said he voted no because a public health problem requires a public health solution. All of the attention on labels is passive and no one reads the label anyway, he added.

Others who voted no questioned whether a label change was necessary as co-prescribing already happens in vulnerable, high-risk groups. Some even raised questions about the cost of co-prescribing as some naloxone products can cost more than $1,000. And others noted that co-prescribing does not address illicit opioid deaths.

Naloxone manufacturers that presented at the advisory committee meeting were all in favor of co-prescribing naloxone with opioids. Adapt Pharma said it hasn't raised the price of Narcan for three years and there are no plans to do so.

December 19, 2018

HHS.gov U.S. Department of Health & Human Services

FOR IMMEDIATE RELEASE
December 19, 2018

Contact: ASH Press Office
202-205-0143
ashmedia@hhs.gov

HHS recommends prescribing or co-prescribing naloxone to patients at high risk for an opioid overdose

Adm. Brett P. Giroir, MD, assistant secretary for health and senior advisor for opioid policy, today released guidance - PDF for healthcare providers and patients detailing how naloxone – the opioid overdose reversal drug – can help save lives and should be prescribed to all patients at risk for opioid complications, including overdose.

"Given the scope of the opioid crisis, it's critically important that healthcare providers and patients discuss the risks of opioids and how naloxone should be used in the event of an overdose," said Adm. Giroir. "We have begun to see some encouraging signs in our response to the opioid crisis, but we know that more work is required to fully reverse the decades-long epidemic. Co-prescribing naloxone when a patient is considered to be at high risk of an overdose, is an essential element of our national effort to reduce overdose deaths and should be practiced widely."

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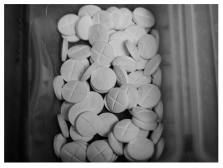
The California Death Certificate Project

- Investigators are going back ***three years to identify any doctors who may have prescribed the drugs inappropriately when someone dies of an overdose death***, even if it was not the fatal dose, and send them letters
- A physician in San Francisco was sent a letter explaining that a patient he had treated died in 2012 from taking a toxic cocktail of methadone and Benadryl — and he was the doctor who wrote the patient's last prescription for methadone
- He had ***two weeks to respond to the letter*** with a written summary of the care he had provided, and a certified copy of the patient's medical record facing fines of $1,000 per day if he didn't comply

TREATMENTS

California Doctors Alarmed As State Links Their Opioid Prescriptions to Deaths

APRIL DEMBOSKY FROM KQED



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Massachusetts Sends Warning to Prescribers

- Letters went to physicians and others identified as having ***prescribed opioids to a patient within 60 days of the patient's death — or to a patient who subsequently died from an opioid overdose***, U.S. Attorney Andrew Lelling said Thursday in a statement

Mass. U.S. Attorney Warning Doctors About Prescribing Opioids

November 30, 2018 | By Steve LeBlanc, The Associated Press

Morphine Sulfate, OxyContin and Opana are displayed for a photograph in Carmichael, California, on Jan. 18, 2013. (Rich Pedroncelli/AP)

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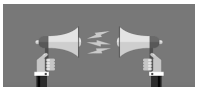
Conclusions

- There are a lot of cooks in the kitchen…



- How does this affect clinical practice?

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You Need to Know…

The 660-Page Opioids Bill Is Now the Law. Here's What's in It.

NOVEMBER 1, 2018

By Billy Wynne, Dawn Joyce

SHARE

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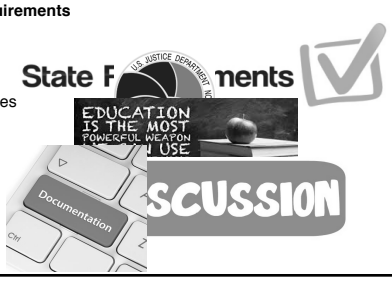
Conclusions

- Start with **state-level requirements**
- Think DEA
- Pro-active **education**
- Discussion
- Consider **societal** outcomes
- Documentation



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"Cure sometimes, treat often, comfort always."
— Hippocrates

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Questions?